

### REMARKS

The Office Action mailed September 7, 2005, rejected all pending claims 1-40. Claims 26-40 have been withdrawn as not elected by Applicants in response to a previous restriction requirement. Claim 18 has been amended to correct a typographical error, which amendment adds no new matter. Accordingly, claims 1-25 are pending and not withdrawn. Applicants respectfully request reconsideration of these claims in view of the following remarks.

#### **Claim Rejections – 35 U.S.C. § 102**

The Office Action rejected independent claims 1 and 18, as well as dependent claims 2-7, 11-13, 19-20, and 24-25 under 35 U.S.C. § 102(e) as being anticipated by Harrison et al. U.S. Patent Publication No. 2004/0167467 A1 (Harrison).

Applicants submit that Harrison does not anticipate the claims of the present application. The fact that Applicants distinguish their claims from Harrison should not be taken as an admission that Harrison is properly considered prior art under any subsection of 35 U.S.C. 102, including 102(e). In addition, because at the time of the present invention, both the present invention and the Harrison reference were subject to be assigned to the same assignee, Scimed Life Systems, Inc., 35 U.S.C. 103(c) provides that Harrison cannot preclude the patentability of the present claim 1 as obvious under 35 U.S.C. 103(a).

#### Claims 1-13

Independent claim 1 is directed to a method of cooling a target tissue region inside a body. The method comprises providing fluid cooled below normal body temperature and blood at a normal body temperature to the tissue region in proportions to cool the tissue region and maintain, for an extended period of time, the temperature of the tissue region within a target temperature range that is below normal body temperature.

Harrison discloses devices and methods to deliver cooled fluid to an internal site in the body. (Abstract). Harrison discloses a method of treating a tissue region by inserting a balloon catheter into a coronary vein that provides access to the tissue region and inflating the balloon to occlude the coronary vein; cooled fluid is delivered from the balloon catheter and distal to the

balloon. (Abstract). In particular, Harrison discloses, as cited in the Office Action in rejecting claim 1, that "a balloon 24 on the shaft 22 may be inflated to provide a seal between the catheter's distal end 34 and, for example, a coronary ostium," that "cooled fluid can be supplied to the ischemic tissue region via the coronary artery," and "[t]he seal prevents cooled fluid delivered to the ischemic tissue region from escaping the coronary artery and entering the aorta, and at the same time, prevents warm blood in the aorta from entering the coronary artery . . . ." (Page 2, paragraph 0032.) Harrison also discloses an implementation where "cooled fluid delivered by a dilation catheter 302 is a saline solution 320," and implementations where "the saline solution 320 could be replaced with blood, a blood substitute, or a mixture of both." (Page 6, paragraph 0063.)

Harrison does not disclose all of the limitations of Applicants' independent claim 1. In particular, Harrison does not disclose, as required by claim 1, a method that includes providing to a target tissue region both fluid cooled below normal body temperature and blood at a normal body temperature to the tissue region in proportions to cool the tissue region and maintain a target temperature range that is below normal body temperature for an extended period of time. Harrison's disclosure at page 2, paragraph 0032, upon which the Examiner relies, does not disclose this aspect of Applicants' claim 1. First, the primary tissue cooling effect in Harrison is achieved by supplying only cooled fluid (whether it be cooled saline or cooled blood) while a catheter is occluding normal blood flow. As such, this aspect of Harrison does not involve providing both cooled fluid and normal-temperature blood to the target tissue region. In addition, while it is true that in Harrison both cooled fluid and normal-temperature blood may be provided to a tissue region when a seal between a catheter's balloon and the blood vessel is removed, the cooled fluid and normal-temperature blood are not provided "in proportions to cool the tissue region and maintain, for an extended period of time, the temperature of the tissue region within a target temperature range that is below normal body temperature," as claim 1 requires.

Furthermore, Harrison's disclosure at page 6, paragraph 0063, which the Examiner also cites in support of his rejection, also does not disclose the method of claim 1. In this paragraph,

Harrison simply discloses replacing the cooled saline solution described previously in Harrison with "blood, a blood substitute, or a mixture of both." While not stated explicitly in this paragraph, it is clear from the context of Harrison that the replacement blood, blood substitute, or mixture would, like the saline, also be cooled. Importantly, Harrison does not disclose providing both cooled fluid and normal temperature blood to the target tissue region.

As discussed previously, Harrison cannot preclude the patentability of claim 1 as obvious, because at the time of the invention both the present invention and Harrison were subject to assignment to the same assignee. 35 U.S.C. § 103(c).

Accordingly, independent claim 1 is patentable in view of Harrison. As such, Applicants ask that the Examiner remove his rejection of independent claim 1, as well as dependent claims 2-7 and 11-13.

#### Claims 18-25

Independent claim 18 is directed to a method of cooling a target tissue region inside a body. The method comprises restricting normal blood flow to the tissue region so that only a desired amount of blood is provided to the tissue region. The method further comprises providing cool fluid to mix with the blood provided to the tissue region so as to cool the tissue region below normal body temperature and to maintain, for an extended period of time, the temperature of the tissue region within a target tissue range that is below normal body temperature.

Harrison does not disclose or suggest all of the limitations of Applicants' independent claim 18. In particular, Harrison does not disclose, as required by claim 18, restricting normal blood flow to the tissue region so that only a desired amount of blood is provided to the tissue region and providing cool fluid to mix with the blood provided to the tissue region to cool the tissue region and maintain a target temperature range for an extended period of time. Harrison does not disclose this aspect of claim 18, for the reasons described previously in connection with claim 1. In addition, as discussed previously, Harrison cannot preclude the patentability of claim 18 as obvious, because at the time of the invention both the present invention and Harrison were subject to assignment to the same assignee. 35 U.S.C. § 103(c).

Accordingly, independent claim 18 is patentable in view of Harrison. Accordingly, Applicants ask that the Examiner remove his rejection of independent claim 18, as well as dependent claims 19-20 and 24-25.

### **Claim Rejections – 35 U.S.C. § 103**

The Office Action rejected claims 8-10, 14-17 and 21-23 under 35 U.S.C. § 103(a) as being obvious over Harrison. As discussed previously, Harrison cannot preclude the patentability of claim 18 as obvious, because at the time of the invention both the present invention and Harrison were subject to assignment to the same assignee. 35 U.S.C. § 103(c).

Accordingly, Applicants ask that the Examiner remove his rejection of claim 8-10, 14-17 and 21-23.

### **Conclusion**

Applicants submit that all pending claims 1-25 are in condition for allowance, and ask that the Examiner issue a notice of allowance.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Applicant : Martin Willard et al.  
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Page : 13 of 13

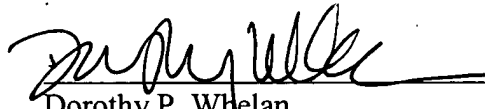
Attorney's Docket No.: 10527-522001 / 03-257

Enclosed is a \$450 check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: \_\_\_\_\_

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